Producer Definition from B.C. Recycling Regulation

"producer" means

(b) in respect of the producer of a product within a product category other than the beverage container product category or the tire product category,

(i) a person who manufactures the product and sells, offers for sale or distributes the product in British Columbia under the manufacturer's own brand,

(ii) if subparagraph (i) does not apply, a person who is not the manufacturer of the product but is the owner or licensee of a trademark under which a product is sold or distributed in British Columbia, whether or not the trademark is registered, or

(iii) if subparagraphs (i) and (ii) do not apply, a person who imports the product into British Columbia for sale, distribution or use in a commercial enterprise;

Producer Definition from Alameda County Safe Drug Disposal Ordinance

"Producer" shall be determined, with regard to a Covered Drug that is sold, offered for sale, or distributed in Alameda County as meaning one of the following:

(i) The Person who manufactures a Covered Drug and who sells, offers for sale, or distributes that a Covered Drug in Alameda County under that Person's own name or brand.

(ii) If there is no Person who sells, offers for sale, or distributes the Covered Drug in Alameda County under the Person's own name or brand, the producer of the Covered Drug is the owner or licensee of a trademark or brand under which the Covered Drug is sold or distributed in Alameda County, whether or not the trademark is registered.

(iii) If there is no Person who is a producer of the Covered Drug for purposes of paragraphs (i) and (ii), the producer of that Covered Drug is the Person who brings the Covered Drug into Alameda County for sale or distribution.

"Producer" does not include:

(i) a retailer that puts its store label on a Covered Drug or

(ii) a pharmacist who dispenses Prescription Drugs to, or compounds a prescribed individual drug product for a consumer.

Producer Definition from WA State Medicine Take-back Bill SSB 5234

"Producer" means the person who:

(a) Has legal ownership of the brand, brand name, or cobrand of the covered drug or manufactures a generic covered drug sold in Washington state.

"Producer" does not include a retailer who puts its store label on a covered drug or a pharmacist who compounds a prescribed individual drug product for a patient;

(b) Imports a covered drug branded or manufactured by a producer that meets the definition under (a) of this subsection and has no physical presence in the United States; or

(c) Sells at wholesale a covered drug, does not have legal ownership of the brand, and elects to fulfill the responsibilities of the producer for that covered drug.

Common usage definitions of pharmaceutical industry terms from various industry websites:

Drug manufacturer – A company that manufactures a drug product. Drug manufacturer is a very broad term which includes companies that use chemical or biological processes to create the final drug product, as well as companies that package, label, process, and format drugs into tablets, liquids, gels, etc.

Contract Manufacturer – A manufacturer that is contracted by another company, which could be a brand owner or private label company, to produce a drug product.

Drug Repacker or Repackager – A company that purchases drug products from the manufacturer and repackages them into smaller quantities, sometimes into unit doses, for pharmacies, clinics, or physicians.

Drug Relabeler – a company that relabels a drug product from a manufacturer to sell it under its own label or brand, or under a private label. Private label products are also referred to as store brand, own brand, private brand, or generic products.

Brand Owner – a company that owns the brand name for a product or line of products, or has proprietary rights to a trademark.

Drug Distributor – also called **Drug Wholesaler**. A company that buys drugs for resale and distribution to companies, pharmacies, and entities other than consumers.

Own-label or Private Label Distributors – a drug distributor that only distributes its own label or brand of drug.

Regulatory Definitions & Terms for Discussion on Defining "Producers" for Product Stewardship Policy

The FDA requires registration of a wide array of entities in the pharmaceutical industry. For each approved drug product in the National Drug Code database, the FDA identifies a single company as the applicant or sponsor. A **drug applicant or sponsor** may be the manufacturer of the drug, or it may be a wholesale distributor of drugs, or it may be a drug repacker or relabeler (entities that are not quite manufacturers and not quite wholesale distributors).

Title 21 – Food and Drugs. 21 CFR 1300, defines manufacture and manufacturer as:

Manufacture means the producing, preparation, propagation, compounding, or processing of a drug or other substance or the packaging or repackaging of such substance, or the labeling or relabeling of the commercial container of such substance, but does not include the activities of a practitioner who, as an incident to his/her administration or dispensing such substance in the course of his/her professional practice, prepares, compounds, packages or labels such substance.

Manufacturer means a person who manufactures a drug or other substance, whether under a registration as a manufacturer or under authority of registration as a researcher or chemical analyst.

States vary in how they define drug manufacturers and drug wholesalers, and whether these definitions include drug repackagers and drug relabelers. WA State's definition of manufacturing and manufacturer are broad.

WA Chapter 69.50 RCW – Uniform Controlled Substances Act defines manufacture as:

(q) "**Manufacture**" means the production, preparation, propagation, compounding, conversion, or processing of a controlled substance, either directly or indirectly or by extraction from substances of natural origin, or independently by means of chemical synthesis, or by a combination of extraction and chemical synthesis, and includes any packaging or repackaging of the substance or labeling or relabeling of its container. The term does not include the preparation, compounding, packaging, repackaging, labeling, or relabeling of a controlled substance:

(1) by a practitioner as an incident to the practitioner's administering or dispensing of a controlled substance in the course of the practitioner's professional practice; or

(2) by a practitioner, or by the practitioner's authorized agent under the practitioner's supervision, for the purpose of, or as an incident to, research, teaching, or chemical analysis and not for sale.

WAC 246-879 - Pharmaceutical Wholesalers defines manufacturer and wholesale distributor as:

"**Manufacturer**" means anyone who is engaged in manufacturing, preparing, propagating, compounding, processing, packaging, repackaging, or labeling of a drug,
provided that a pharmacist compounding drugs to be dispensed from the pharmacy in which the drugs are compounded pursuant to prescriptions for individual patients shall not be considered a manufacturer.

"**Wholesale distributor**" means anyone engaged in wholesale distribution of drugs, including but not limited to, manufacturers; repackers; own-label distributors; private-label distributors; jobbers; brokers; warehouses; including manufacturers' and distributors' warehouses, chain drug warehouses, and wholesale drug warehouses; independent wholesale drug traders; and retail pharmacies that conduct wholesale distributions.